GAO Report Finds FDAÃ¢â‚¬â„¢s Foreign Drug Inspection Program Needs Significant Improvement

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GAO Report Finds FDA's Foreign Drug Inspection Program Needs Significant Improvement
Better Data Management, More Inspections Necessary to Protect U.S. Consumers

Washington, D.C.
- A Government Accountability Office (GAO) report released today found better data management and more inspections are needed to strengthen the Food and Drug Administration's (FDA) foreign drug inspection program. The report was requested by Reps. John D. Dingell (D-MI) and Joe Barton (R-TX), Chairman and Ranking Member of the Committee on Energy and Commerce, Bart Stupak (D-MI) and John Shimkus (R-IL), Chairman and Ranking Member of its Subcommittee on Oversight and Investigations, Senator Charles Grassley (R-IA), Ranking Member of the U.S. Senate Committee on Finance, and Rep. Ed Whitfield (R-KY), Ranking Member of the Committee on Energy and Commerce's Subcommittee on Commerce, Trade and Consumer Protection.

The
lawmakers asked GAO to assess (1) the extent to which FDA has accurate data on the number of foreign establishments subject to inspection, (2) the frequency of foreign inspections, and (3) oversight by FDA to ensure that foreign establishments correct serious problems identified during inspections. GAO analyzed information from FDA databases,

reviewed inspection reports which identified serious deficiencies, and interviewed FDA officials.

"This report confirms that we have reason to be concerned about the safety of imported drugs," said Dingell. "Foreign inspections are alarmingly low and I'm especially disturbed that decisions about which foreign facilities are inspected is driven by drug approval process instead of surveillance needs. In light of this report, we will continue our work to ensure that FDA has the resources and authority necessary to fulfill its mission and protect American consumers."

"The subcommittee's investigation over the past two years has found that the drugs Americans are increasingly relying upon are made outside of the U.S. and often in countries that lack any semblance of suitable regulatory system," Stupak said. "GAO's study confirms that the system deployed by FDA to police those facilities and keep Americans safe from poorly manufactured drugs is understaffed, overwhelmed, and completely inadequate."

"This report underscores the importance of Congress acting on reforms to improve FDA's foreign inspection system and of the FDA itself making aggressive moves to strengthen serious weaknesses in the foreign inspections process," said Grassley.

In July, Grassley and Senator Ted Kennedy (D-MA) introduced the "Drug and Device Accountability Act of 2008. " The proposal, S.3409, would improve FDA's oversight of pharmaceutical drugs and medical devices by enhancing registration of drug and device facilities, so FDA knows how many foreign facilities are exporting to the United States and thus subject to inspection. It would also increase resources through the collection of user fees from manufacturers so that FDA can conduct more inspections of overseas facilities. The Senate bill is part of an effort to ensure that America's increasingly foreign-produced drug and device supply is safe and effective.

"The phenomenon of killer drugs from suspicious places caught everybody's attention this year, and now GAO has confirmed much of the bad news we got in multiple hearings," Barton said. "The FDA is taking steps to address some of the problems by investing in new information systems and creating field offices to increase the agency's international presence. Those actions are helpful, but much more needs to be done so Americans can rely absolutely on the safety of the medicines they take to make them well. There isn't any daylight between Republicans and Democrats on the core issue, and that's why Chairman Dingell and I have been able to work closely to develop legislation on safety of imported drugs. I look forward to moving a bill when Congress returns."

"For quite some time we have known the FDA lacks the resources and man power needed for foreign drug manufacturer inspections," said Shimkus. "While we work to provide all the tools the agency needs, FDA should continue to build on a risk-based system to prioritize inspections where they are needed most."

"This GAO report and the numerous hearings held by the House Energy and Commerce Committee have made it abundantly clear that the FDA lacks the resources to effectively inspect foreign facilities and safeguard the American people," said Whitfield. "It is essential that the FDA have a comprehensive oversight program in place to ensure the safety and quality of the drugs we allow into our country. I am hopeful that the FDA will be provided the additional resources to increase their inspection presence in foreign countries and make critical improvements to their inspections program, particularly in terms of the frequency of their inspections and management of the data collected."

GAO found that FDA databases contain inaccurate information on foreign establishments subject to inspection and that FDA inspects relatively few foreign establishments each year. While FDA inspects domestic drug manufacturers every 2.7 years, FDA is only inspecting foreign manufacturers every 13 years, despite the fact that serious violations are often found in foreign facilities. Additionally, FDA is failing to follow-up promptly with repeat inspections after serious violations are found in foreign facilities. In fact, for three facilities charged with safety violated, FDA did not make return visits until 4-5 years after initial warning letters were issued.

GAO recommends that FDA improve the data that it uses to manage its foreign inspection program, conduct more inspections of foreign establishments, and ensure more timely inspection of foreign establishments where FDA has identified serious deficiencies.

For more information about the Committee's ongoing drug safety investigation visit: http://energycommerce.house.gov/Investigations/FDADrugSafety.shtml

During this Congressional session, Committee leaders released draft legislation aimed at improving the safety of food, drugs, devices, and cosmetics. Work in this draft bill, the "Food and Drug Administration Globalization Act," continues. Committee leaders plan to introduce a comprehensive legislation early next session. For more information

visit: http://energycommerce.house.gov/FDAGlobalAct-08/index.shtml

For
a copy of today's GAO report on "DRUG SAFETY: Better Data Management and More Inspections Are Needed to Strengthen FDA's Foreign Drug Inspection Program" click here

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